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Anmelder/Applicant/Demandeur/Patentinhaber/Proprietor/Titulaire
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NOTIFICATION D'OPPOSITIONS (REGLE 57(1) CBE)

Dans le délai d'opposition, une opposition(~~des oppositions~~) a (~~ont~~) été formée(~~s~~) par:

01. Siemens-Elema AB/Landsvägen 32/17239 Sundbyberg/SE

L'(~~Les~~) opposition(~~s~~) énumérée(~~s~~) ci-dessus vous a (~~ont~~) déjà été signifiée(s).

Nous vous invitons, dans un délai de 4 mois à compter de la signification de la présente notification, à présenter vos observations, en ayant soin d'en produire des copies en 1 exemplaire(s) pour les autres parties à la procédure (règle 36(4) CBE).

Les cas échéant, il vous est possible de déposer également des modifications de la description, des revendications et des dessins dans le délai indiqué. Ces pièces doivent être produites sur des feuilles séparées, en trois exemplaires pour l'OEB, et en 1 exemplaire(s) pour les autres parties à la procédure (règle 36(1) et (4) CBE).

Si mention est faite de documents qui n'ont pas encore été mentionnés au cours de la procédure, il vous appartient de fournir ces documents en deux exemplaires (cf. règle 59 CBE).

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Annexes:

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Our Ref. GR 17/782 462
Date February 22, 2000

European Patent Application No.: 95930565.7
Publication No.: 0 782 462
Patentee: Nellcor Puritan Bennett France Développement
91975 Courtabouef Cedex (FR)
Title: Pressure-controlled breathing aid

We, Siemens-Elema AB, SE, do hereby file an

OPPOSITION

against the above identified patent.

The opposition fee can be debited against Siemens AG's deposit account No. 2 800 0003, according to a separate debit order from Siemens AG.

We request that the above-identified European Patent be revoked in its entirety.

The opposition is based on the grounds stated in Art. 100(a) EPC.

If our request is not allowed, we hereby request for oral proceedings according to Art. 116 EPC.

The following prior art is referred to:
D1 = System SV 300; New modes - PRVC and VS; November 1993
D2 = Servo Ventilator 300; Operating Manual; May 1993
D3 = Servo Ventilator 300; Service Manual - Preliminary; February 1994

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D4 = FR 2 695 830
D5 = EP 402 951
D6 = US 5 129 390

Reasons:

I.

Claim 1 of the opposed patent relates to a pressure mode breathing aid device, comprising
a) means of detecting during operation of the device the breathing activity of a patient and of generating, as a function of that activity, inspiration and expiration phases synchronised with the said activity,
b) means (8) for supplying during operation of the device breathable gas, during the inspiration phases, to an inspiratory branch (3) of a patient circuit (1) at an inspiratory pressure adjusted in relation to a command (AI) for the inspiratory pressure prevailing in the inspiratory branch (3), and characterised by:
c) means (12; 32; 42) of measuring the breathed volume,
d) means of comparing the breathed volume (VTI; VTE) with a volume command (VTImini; VTEmini), and
e) regulating means (11) to increase the inspiratory pressure command (AI) in the case of a breathed volume lower than the volume command (VTImini; VTEmini), and to reduce the inspiratory pressure command (AI) in the case of a breathed volume higher than the volume command (VTImini; VTEmini) so that said command (AI) is adjusted for fulfilling a flow rate condition.

D1 - D3 all describe the same apparatus, Servo Ventilator 300. In D1 [page 2] there is a reference to both the Operating Manual (D2) and the Service Manual (D3) for in-depth and technical information. These references are therefore linked so as to form a whole. The information provided D1 - D3 is therefore possible to use for both Art. 54 and 56 EPC purposes.

The Servo Ventilator 300 is generally described in D2, pages 16-17 and D3, pages 10-17. Ventilation modes are described on pages 77-98 in D2, whole of D1 and pages 33-36 in D3.

The Servo Ventilator 300 is a pressure mode breathing aid device, comprising
a) means of detecting during operation of the device the breathing activity of a patient and of generating, as a function of that activity, inspiration and expiration phases synchronised with the said activity [e.g. D1, page 8-9],
b) means for supplying during operation of the device breathable gas, during the inspiration phases, to an inspiratory branch of a patient circuit at an inspiratory pressure adjusted in relation

to a command for the inspiratory pressure prevailing in the inspiratory branch [e.g. D3, pages 15-16], and further comprises:

c) means of measuring the breathed volume [D1, page 9, D2, page 84 and D3, page 34],

d) means of comparing the breathed volume with a volume command [D3, page 34], and

e) regulating means to increase the inspiratory pressure command in the case of a breathed volume lower than the volume command, and to reduce the inspiratory pressure command in the case of a breathed volume higher than the volume command so that said command is adjusted for fulfilling a flow rate condition [D3, pages 15 and 35].

D6 also disclose a device which can synchronise inspiration and expiration phases with breathing activity of the patient. It supplies gas to an inspiratory branch during inspiration, adjusted in relation to an inspiratory pressure command. It measures breathed volume and compares it with a volume command. It comprises regulating means for increasing the inspiratory pressure command in the case of a breathed volume higher than the volume command so that said command is adjusted for fulfilling a flow rate condition. [essentially Figs. 1, 5a, 5b, 5d and 5e + col. 2, lines 51-55; col. 3, lines 7-18; col. 4, lines 35-63; col. 5, line 21 -col. 6, line 19; col. 8, line 66 - col. 9, line 28; and col. 10, lines 20-60.]

In view of any of D1 - D3 and D6, the subject matter according to claim 1 is not novel.

D4 discloses a device according to the preamble of claim 1. This reference is also mentioned in the specification of the opposed patent [col. 2, lines 46-50] as being of a type of device with which the invention is particularly compatible and actually forms the basis for the preamble to claim 1. From FIG. 3 and corresponding portion of the description, page 11, line 33 - page 12, line 10, it is also obvious that the device of D4 comprises means for measuring the breathed volume (flow meter 18 and microprocessor 12).

The problem to solve, is to achieve a device which combines the advantages of volume controlled and pressure controlled breathing modes.

From any of D1-D3 such a combined mode is known. It is clearly stated in D1, page 3 (for instance) that the supported pressure is automatically regulated until the patient receives the pre-set target tidal/minute-volume.

Implementation of this mode into the device of D4 does not pose any problems to the skilled person. The microprocessor 12 can without any due burden be programmed (for instance) to carry out the comparison disclosed in D3, page 34.

D5 discloses a pressure mode breathing aid device for assisting the spontaneous breathing of a patient. It detects and follows the breathing activity and supplies breathing gas [mainly col. 1 and col. 2] at a pressure adjusted in relation to a command. [Mainly col. 1, line 3 - col. 2, line 13.]

The device in D5 further comprises means for measuring breathed volume [col. 2, line 51 - col. 3, line 4] and regulating means for regulating pressure based on measured flow [col. 3, lines 5-28]. It is further stated here that obtained tidal volume and minute volume can be used for obtaining more proper tidal volume and minute volume. It is also stated that imposed work of breathing (which is based on airway pressure and tidal volume) can set at a desired level and airway pressure being automatically set. It is implicit that with a fixed tidal volume for achieving the desired work of breathing, the pressure may be varied in the same way as stated in claim 1.

In view of the mode ventilator support as disclosed in D1 - D3, it would be obvious to the skilled person to implement this mode in the device of D5.

The subject matter of claim 1 does therefore not involve an inventive step.

II.

Claim 2 of the opposed patent includes the further features that the means (12; 32; 42) for measuring the breathed volume measure the volume amount (VTI; VTE) breathed by the patient during a breathing cycle, and the regulating means (11) are based on the result of the comparison (12) of this volume amount with the volume command in order to adjust the inspiratory pressure applied during a following cycle.

This is implicit from D1 [page 9], D2 [page 84] and D3 [page 34]. It is also implicit from D6 [col. 10, lines 41-42].

Claim 2 is therefore not novel.

In view of the combination of any of D3 and D5 with any of D1 - D3, claim 2 does not involve an inventive step.

III.

Claim 3 of the opposed patent is dependent on claim 1 or 2 and includes the further feature that the means (12; 42) for measuring the breathed volume measure the volume (VTI) inspired by the patient.

This is implicit from D1 [page 9], D2 [page 84] and D3 [page 34]. It is also implicit from D6 [col. 10, lines 41-42].

Claim 3 is therefore not novel.

In view of the combination of any of D3 and D5 with any of D1 - D3, claim 3 does not involve an inventive step.

IV.

Claim 4 of the opposed patent is dependent on claim 1 or 2 and includes the further feature that the means (12; 42) for measuring the breathed volume measure the volume (VTE) expired by the patient.

The device according to D2 comprises [page 16-17] a flow meter for measuring expired flow and [page 65] also calculates expired volumes. Essentially, there is no difference whether inhaled or exhaled volumes are measured and utilised. In particular not when spontaneously breathing patients are considered. If the patient doesn't exhale the inhaled amount, there will be a pressure build up (with risk of barotrauma) or a pressure depletion (with risk of lung collapse).

D5 explicitly measures flow to and from the patient [flow meter 1a in Figs. 1 and 2]. Based on the flow, the inhaled and exhaled volumes can be determined.

D6 explicitly states that both inspired and expired tidal volumes can be obtained [col. 8, lines 8-16].

Claim 4 does therefore not involve an inventive step.

V.

Claim 5 of the opposed patent depends on claim 1 or 2 and includes the further feature that the means (42) of measuring the breathed volume selectively measure the volume inspired (VTI) or the volume expired (VTE).

In view of the reasons discussed under points **III.** and **IV.** Claim 5 lacks novelty/inventive step.

VI.

Claim 6 of the opposed patent is dependent on claim 3 and includes the further feature of means (8) for connecting the inspiratory branch in substantially gas-tight manner with the respiratory channels of the patient during inspiratory phases of the respiratory cycle and to interrupt the flow of breathable gas in the inspiratory branch (3) during expiratory phases of the respiratory cycle, and in that the means (12) of measuring the breathed volume are connected to the inspiratory branch (3).

These features represent straightforward and reasonable steps that are normally taken in the relevant art. For instance, they are present in D4.

Claim 6 does not involve an inventive step.

VII.

Claim 7 of the opposed patent is dependent on claim 4 and includes the further feature of the patient circuit (1) comprises an expiratory branch (4) and in that the device comprises means (5) of connecting the expiratory branch (4) in substantially gas-tight manner with the respiratory channels of the patient during expiratory phases of the respiratory cycle and to interrupt the flow of gas in the expiratory branch (4) during inspiratory phases of the respiratory cycle, and in that the means (32) of measuring the breathed volume are connected to the expiratory branch (4).

These features represent straightforward and reasonable steps and would be taken if exhaled volume were to be measured. Implicitly, they are present in D1 - D3 and in D5.

Claim 7 does not involve an inventive step.

VIII.

Claim 8 of the opposed patent is dependent on claim 5 and essentially includes the further feature that the means for measuring the breathed volume is disposed in a bi-directional branch connected to the inspiratory and expiratory branches.

This feature is evident from D5 and D6.

Claim 8 does not involve an inventive step.

IX.

Claim 9 of the opposed patent is dependent on any of the claims 1-8 and essentially includes the further feature that the inspiratory pressure (AI) is increased when breathed volume (VTI, VTE) is less than the volume command (VTImini, VTEmini) and the inspiratory pressure command (AI) is less than a predetermined maximum pressure (AImaxi).

This feature is present in all of D1 - D3.

Claim 9 is therefore not novel/does not involve an inventive step.

X.

Claim 10 of the opposed patent is dependent on any of the claims 1-9 and essentially includes the further feature that the inspiratory pressure (AI) is decreased when breathed volume (VTI, VTE) is higher than the volume command (VTImini, VTEmini) and the inspiratory pressure command (AI) is higher than a predetermined minimum pressure (AImini).

This feature is present in all of D1 - D3 and implicit from D6.

Claim 10 is therefore not novel/does not involve an inventive step.

XI.

Claim 11 of the opposed patent is dependent on any of the claims 1-10 and essentially includes the further feature that in at least certain of cases the inspiratory pressure is varied based on difference between measured breathed volume and volume command.

This feature is present in all of D1 - D3 and implicit from D6.

Claim 11 is therefore not novel/does not involve an inventive step.

XII.

Claim 12 of the opposed patent is dependent on claim 11 and essentially includes the further feature that the variation in pressure is equal in percentage to the difference between measured breathed volume and volume command.

From D3 [page 34] it is clear that the pressure variation can be based on the quotient between set tidal volume and measured tidal volume. There is no criticality or inventive significance in using a more strict percentage difference between volumes than the direct quotient. It is a matter of choice for the skilled person.

Claim 12 does therefore not involve an inventive step.

XIII.

Claim 13 of the opposed patent is dependent on any of the claims 1-10 and essentially includes the further feature that the inspiratory pressure cannot exceed a predetermined extreme value.

This is clearly shown in D1 - D3 and D6.

Claim 13 is therefore not novel/does not involve an inventive step.

XIV.

Claim 14 of the opposed patent is dependent on claim 9 or 13 and essentially includes the further feature of means for indicating the simultaneous occurrence of a breathed volume (VTI; VTE) below the volume command (VTImini; VTEmini) and an inspiratory pressure (AI) at least equal to a predetermined maximum pressure.

From D2 [page 63] it is obvious that an alarm will be generated if a set tidal volume is not obtained with maximally allowed pressure in 3 consecutive breaths. Internally in the device, there is thus an indication that breathed volume is lower than the volume command at the predetermined maximum pressure. There is no criticality or inventive significance in indicating a first occurrence of this condition to a user instead of a third consecutive occurrence. It is a matter of choice for the skilled person.

Our request is therefore proper.

Siemens-Elema AB

Samzelius

General Authorisation No. 3591

Enclosures:
Evidence (twofold)